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Page 1 of 5

| Examiner's Initials | US Patent Document | Name of Patentee or applicant of cited document | Date of Publication of Cited Document | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
|---------------------|----------------------|---|---------------------------------------|--|
| JCS | 4,830,010 | Marshall | 05-16-1989 | |
| | 5,074,594 | Laganowski | 12-24-1991 | |
| KSS | 5,364,793 | Cameron, Sr. et al. | 11-15-1994 | |
| JCS | 5,524,622 | Wilson | 06-11-1996 | |
| KSS | 5,814,455 | Pronovost Pronovost et al. | 09-29-1998 | |
| JCS | 5,879,897 | Koufman | 03-09-1999 | |
| KSI | 6,067,989 | Katzman | 05-30-2000 | |
| KSS | 6,068,985 | Cripps et al. | 05-30-2000 | |
| JCS | 6,090,611 | Covacci, et al. | 07-18-2000 | |
| | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner's Initials | Cite No. | office | Number | Kind Code | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document | Pages where relevant passages appear | T ⁶ |
|---------------------|----------|--------|--------|-----------|---|---------------------------------------|--------------------------------------|----------------|
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Khaled S. S. S.

3/20/01

1. Harris A, Dyspepsia and Helicobacter pylori: test, treat or investigate? Eur J Gastroenterol Hepat 1999; 11 (Suppl 1): S31-5.
2. Working Party of the Clinical Services Committee of the British Society of Gastroenterology. Provision of gastrointestinal endoscopy and related services for a district general hospital. Gut 1991; 32: 95-105.
3. Gear MWL, Wilkinson SP, Open access upper alimentary endoscopy. Br J Hosp Med 1989; 41: 438-44.
4. Bodger K, Wyatt JL, Heatley RV, Serologic screening before endoscopy: The value of Helicobacter pylori serology, serum recognition of the CagA and VacA proteins, and serum pepsinogen I, Scand J Gastroenterol 1999; 34: 856-63.
5. Moayyedi P, Zilles A, Clough M, Hemingbrough E, Chalmers DM, Axon AT, The effectiveness of screening and treating Helicobacter pylori in the management of dyspepsia, Eur J Gastroenterol Hepatol 1999; 11:1245-50.
6. Chiba N, Lahaie R, Fedorak RN, Bailey R, Veldhuyzen van Zanten SJ, Bernucci B, Helicobacter pylori and peptic ulcer disease. Current evidence for management strategies, Can Fam Physician 1998; 44: 1481-8.
7. Genta RM, Acid suppression and gastric atrophy: sifting fact from fiction, Gut 1998; 43: 35-8. Suppl. 1
8. ~~Coyle WJ, Lawson JM~~ ^{Fseld k- et al}, Helicobacter pylori infection in patients with early gastric cancer by the endoscopic phenol red test, Gastrointest Endosc 1998; 48: 327-8.
9. Lee BM, Jang JJ, Kim JS, You YC, Chun SA, Kim HS, et al., Association of Helicobacter pylori infection with gastric adenocarcinoma, Jpn J Cancer Res 1998; 89: 597-603.

3/20/01

10. Ozasa K, Kurata JH, Higashi A, K. Hayashi K, Inokuchi H, Miki K, et al., *Helicobacter pylori* infection and atrophic gastritis: a nested case-control study in a rural town in Japan, *Dig Dis Sci* 1999; 44: 253-6.

11. Bech K, Hoier-Madsen M, Feldt-Rasmussen U, Jensen BM, Molsted-Pedersen L, Kuhl C, Thyroid function and autoimmune manifestations in insulin-dependent diabetes mellitus during and after pregnancy, *Acta Endocrinol* 1991; 124: 534-9.

12. Barrio R, Roldan MB, Alonso M, Canton R, Camarero C, *Helicobacter pylori* infection with parietal cell antibodies in children and adolescents with insulin dependent diabetes mellitus, *Pediatr Endocrinol Metab* 1997; 10: 511-6.

13. Datta A, Deodhar SD, Datta U, Sehgal S, Non-organ specific & organ specific antibodies in rheumatoid arthritis, *Indian J Med Res* 1990; 92: 228-32.

14. Mårdh S, Ma JY, Song YH, Aly A, Henriksson K, Occurrence of autoantibodies against intrinsic factor, H,K-ATPase and pepsinogen in atrophic gastritis and rheumatoid arthritis. *Scand J Gastroenterol* 1991; 26: 1089-96.

15. Karlsson A, Burman P, Löf L, Mårdh S, Major parietal cell antigen in autoimmune gastritis with pernicious anemia is the acid-producing H,K-adenosine triphosphatase of the stomach, *J Clin Invest* 1988; 81: 475-9.

16. Song YH, Ma JY, Mårdh S, Liu T, Sjöstrand SE, Rask L et al., Localization of a pernicious anemia-autoantibody epitope on the α -subunit of the human H,K-ATPase. *Scand J Gastroenterol* 1994; 29: 122-7.

~~17. Ma JY, Borch K, Mårdh S, Human gastric H,K-adenosine triphosphatase β -subunit is a major autoantigen in atrophic corpus gastritis. Expression of the recombinant human glycoprotein in insect cells. *Scand J Gastroenterol* 1994; 29: 790-4.~~

18. Baron JH, Clinical tests of gastric secretion: History, Methodology and Interpretation. (1978) London: Macmillan.

Kimble & S
3/20/01

19. Samloff IM, Liebman WM, Panitch NM, Serum group I pepsinogens by radioimmunoassay in control subjects and patients with peptic ulcer. Gastroenterol 1975 Jul; 69(1): 83-90.

KN 20. Samloff IM, Varis K, Ihamaki T, Siurala M, Rotter JJ, Relationships among serum pepsinogen I, serum pepsinogen II, and gastric mucosal histology. A study in relatives of patients with pernicious anemia. Gastroenterol 1982 Jul; 83(1 Pt 2): 204-9.

KN 21. Borch K, Stridsberg M, Burman P, Rehfeld JF, Basal chromogranin A and gastrin concentrations in circulation correlate to endocrine cell proliferation in type A gastritis. Scand J Gastroenterol 1997; 32:198-202.

KN 22. Carmel R, Pepsinogens and other serum markers in pernicious anemia. Am J Pathol 1998; 90: 442-5. *of Clinical*

KN 23. Waters HM, Smith C, Howarth JE, Dawson DW, Delamore IW, New enzyme immunoassay for detecting total, type I, and type II intrinsic factor antibodies. J Clin Pathol 1989; 42: 307-12.

~~24. Mårdh S, Song Y-H, Characterization of antigenic structures in autoimmune atrophic gastritis with pernicious anemia. The parietal cell H,K-ATPase and the chief cell pepsinogen are the two major antigens. Acta Physiol Scand 1989; 136: 581-7.~~

KN 25. Borch K, Liedberg G, Prevalence and incidence of pernicious anemia. An evaluation for gastric screening. Scand J Gastroenterol 1984; 19: 154-60.

KN 26. Borch K, Jönsson K-Å, Redéen S, Petersson F, Mårdh S, Franzén L, Prevalence of gastroduodenitis and Helicobacter pylori infection in the general population: Relations to symptomatology and life style. Dig Dis Sci, 2000, 45: 1322-29.

KN 27. Price A, The Sydney system: Histological division, J Gastroenterol Hepatol 1991; 6: 209-22.

KN 28. Dixon MF, Genta RM, Yardley JH, Correa P, the Participants in the International Workshop on the Histopathology of Gastritis, Houston 1994. Classification and grading of gastritis. The updated Sydney system, Am J Surg Pathol 1996; 20: 1161-81.

Kenner 3/20/01

29. Karlsson FA, Burman P, Lööf L, Olsson M, Scheynius A, Mårdh S, Enzyme-linked immunosorbent assay of H,K-ATPase, the parietal cell antigen. Clin exp Immunol 1987; 70:604-10.

30. Ma J-Y, Borch K, Sjöstrand SE, Janzon L, Mårdh S, Positive correlation between H,K-adenosine triphosphatase autoantibodies and Helicobacter pylori antibodies in patients with pernicious anemia. Scand J Gastroenterol 1994; 29: 961-6.

31. Forné Montserrat, et al, Accuracy of an Enzyme Innunoassay for the Detection of *Helicobacter pylori* in Stool Specimens in the Diagnosis of Infection and Posttreatment Check-Up

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